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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/356,322	11/24/1998	TIDHAR DARI SHALON	STFD:009--1	7679

7590 09/30/2003

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EXAMINER
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MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/30/2003

38

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/356,322

Applicant(s)

SHALON ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2003 and 08 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Applicants' arguments, filed 3/3/03 and 7/8/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### **NEW MATTER**

Claims 34, 35, and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The NEW MATTER rejection based on the NEW MATTER in the phrase "essentially free of cross-contamination..." still remains regarding claim 34 and those dependent therefrom due to their dependence. This rejection therefore is maintained and reiterated from the previous office action, mailed 10/1/02. The inherency argument regarding applying a DNA solution to each region of a microarray has previously been responded to as being non-persuasive regarding this issue. No other argument has been set forth other than the amendment to claim 7, which does not remove the NEW MATTER from claim 34, however.

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### **PRIOR ART**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung et al. (WO 90/15070).

This rejection is maintained and reiterated from the previous office action, mailed 10/1/02. Applicants argue that the reference primarily teaches a method of peptide synthesis on a substrate and only lists nucleic acids as one example among many other possible polymers and that there is no disclosure at all of DNA sequences. In response nucleic acids are extremely well known to encompass DNA sequences. This argument is therefore non-persuasive. Applicants then argue that the disclosure cannot be enabling for DNA sequence preparation of a microarray. In response the above admission by applicants firstly indicates that nucleic acid microarrays are suggested by the reference which is also deemed to include DNA polymers or sequences. DNA immobilization technology is old in the art and guided by the above description of

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attaching nucleic acids (such as DNA) onto a surface the reference does not need to supply any more detailed description of what is old in the art for enablement.

Applicants then argue with firstly the admission that the reference describes immobilization of various biochemicals including nucleic acids, but that such a polymer is not part of the substrate (bolded argument). In response the substrate as instantly claimed, for example, in claim 7 merely requires a surface which comprises DNA sequences. No limitation is present regarding what manner of comprising is practiced. Therefore, any attachment practice including non-covalent binding, such as hybridization or receptor recognition to result in association with a substrate surface results in a surface which then "comprises" a microarray of DNA sequences. No claim limitation is present in claim 7 regarding covalent attachment, for example. Therefore the immobilized nucleic acids of the reference sufficiently support this rejection as describing a reasonable embodiment of the instant claims. It is noted that covalent attachment is actually required in instant claim 14, however, this was described in the reference as already set forth in the basis description of this rejection in the previous office action, mailed 10/1/02. Applicants then argue that the length of a DNA in the range of 8-10 bases prevents selective hybridization with a specific polynucleotide in a mixture. In response, this is an allegation without factual support and therefore non-persuasive. Another response to this argument is that primers in the 8-10 base length range are well known in the art for selective hybridization to specific polynucleotides in a mixture during amplification reactions. Applicants then argue that the reference does not describe the individual application of DNA to each region in a microarray. This

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argument is based on a method of making limitation regarding how each region of a microarray is made to contain a specific DNA sequence. Such process limitations do not distinguish a reference that makes a microarray by a different process wherein the microarray made and instantly claimed is indistinguishable from that made by the process of the reference. Applicants then argue regarding the lack of cross-contamination of regions and allege that the reference supplies no evidence or indication that the reference substrate has a substantially pure polymer within a defined region. In response the reference clearly shows and describes microarray preparation with the intended usage of sample binding assays wherein each region will result in a different binding reaction result so that analysis of a multitude of different binding reactions may be performed in parallel. This would be impossible if each predefined region did not contain substantially pure polymers which were essentially free of cross-contamination. This argument, therefore, is non-persuasive.

**THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 27, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER